DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL

FOR: HEALTH CARE FINANCING ADMINISTRATION

1. TRANSMITTAL NUMBER: 0 3 — 0 5 M A

2. STATE: N J

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)

TO: REGIONAL ADMINISTRATOR
HEALTH CARE FINANCING ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE
July, 1, 2003

5. TYPE OF PLAN MATERIAL *(Check One)*:

☐ NEW STATE PLAN ☐ AMENDMENT TO BE CONSIDERED AS NEW PLAN ☒ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT *(Separate Transmittal for each amendment)*

6. FEDERAL STATUTE/REGULATION CITATION:
42CFR447, generally; 42CFR447.201 and
42CFR447.331, specifically
P&I

7. FEDERAL BUDGET IMPACT: (See Attached)
a. FFY 2003 $(1,680,967)
b. FFY 2004 $(21,798,734)

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:
Addendum to Attachment 3.1A, page 12(a)
Addendum to Attachment 3.1A, page 12(a).1
Addendum to Attachment 3.1B, page 12(a)
Addendum to Attachment 3.1B, page 12(a).1
Attachment 4.19-B, page 10
Attachment 4.19-B, page 10(d)

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*:
SAME

10. SUBJECT OF AMENDMENT:
Budget-Related Pharmacy Amendments

11. GOVERNOR'S REVIEW *(Check One)*:

☐ GOVERNOR'S OFFICE REPORTED NO COMMENT
☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL
☒ OTHER, AS SPECIFIED:
Not required, per State Plan

12. SIGNATURE OF STATE AGENCY OFFICIAL:
Gwendolyn L Harris

13. TYPED NAME:
Gwendolyn L. Harris

14. TITLE:
Commissioner

15. DATE SUBMITTED:
9-16-03

16. RETURN TO:
Jean Cary
DMAHS
P.O. Box 712, #26
Trenton, NJ 08625-0712

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED:

18. DATE APPROVED:
April 16, 2004

PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL:
July 1, 2003

20. SIGNATURE OF REGIONAL OFFICIAL:

21. TYPED NAME:
Sue Kelly

22. TITLE:
Associate Regional Administrator
Division of Medicaid and State Operations

23. REMARKS: "Originally submitted pages have been replaced by revised pages per discussions, e-mails, letters, and negotiations between CMS and State".

Pen & Ink Change Requested by State

Addendum to Attachment 3.1A, page 12(a)
Addendum to Attachment 3.1A, page 12(a).1
Addendum to Attachment 3.1B, page 12(a)
Addendum to Attachment 3.1B, page 12(a).1
Attachment 4.19-B, page 10
Attachment 4.19-B, page 10(a)
Attachment 4.19-B, page 10(b)
Attachment 4.19-B, page 10(c)
~~Attachment 4.19-B, page 10(d)~~

FORM HCFA-179 (07-92)

Instructions on Back

OFFICIAL

Savings	State	Federal	Gross
AWP from 10% to 12.5%	$ (5,622,000)	$ (5,337,064)	$ (10,959,064)
Mandatory Generics	$ (12,958,000)	$ (12,301,259)	$ (25,259,259)
Rebates on Carve Out	$ (9,776,738)	$ (9,776,738)	$ (19,553,475)

Cost	State	Federal	Gross
ABD Carve Out	$ 5,616,323	$ 5,616,323	$ 11,232,646

AWP minus 12.5%

For the Federal Fiscal Year 2003, that is, from July 1, 2003, to September 30, 2003, the anticipated Federal savings for AWP minus 12.5% (effective July 1, 2003) is $1,334,266.

For the Federal Fiscal Year 2004, that is, from October 1, 2003 to September 30, 2004, the anticipated Federal savings for AWP minus 12.5% is $5,337,064.

Mandatory Generics

For the Federal Fiscal Year 2004, that is, from October 1, 2003 to September 30, 2004, the anticipated Federal savings for mandatory generics (effective October 1, 2003) is $12,301,259.

ABD Carve Out

For the Federal Fiscal Year 2003, that is, from September 1, 2003, to September 30, 2003, the anticipated Federal cost for ABD Carve Out (effective September 1, 2003) is $468,027. However, for the same period, the additional rebates the State will receive as a result of the ABD Carve Out will generate $814,728 in Federal savings, resulting in a net anticipated Federal savings for this initiative of $346,701.

For the Federal Fiscal Year 2004, that is, from October 1, 2003, to September 30, 2004, the anticipated Federal cost for ABD Carve Out is $5,616,323. However, for the same period, the additional rebates the State will receive as a result of the ABD Carve Out will generate $9,776,738 in Federal savings, resulting in a net anticipated Federal savings for this initiative of $4,160,415.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
LIMITATIONS ON AMOUNT, DURATION AND SCOPE OF SERVICES PROVIDED TO THE CATEGORICALLY NEEDY

12(a) Pharmacy services

Coverage for drugs is available, limited to the following:

Multisource generic and single source brand name drugs shall be dispensed without prior authorization, unless otherwise required by the Medical Exception or drug utilization review (DUR) process. Multisource brand name drugs shall not be dispensed without prior authorization by the State. However, a ten (10) day supply of the multisource brand name drug shall be dispensed pending receipt of prior authorization. Multisource brand name drugs with a narrow therapeutic index, other drugs recommended by the NJ Drug Utilization Review Board, or brand name drugs with a lower cost per unit than the generic drug may be excluded from prior authorization, as determined by the Commissioner. In emergency situations, providers may dispense at least a seventy-two hour supply of medication. The prior authorization process provides for a turn-around response by either telephone or other telecommunications device within twenty-four hours of receipt of a prior authorization request.

Covered outpatient drugs from any manufacturer that has entered into and complies with an agreement with the State on the same basis as provided under Section 1927(a) through (c) of the Act, which are prescribed for a medically accepted diagnostic indication (as provided by Section 1927(d) of the Act, certain outpatient drugs may be excluded from coverage).

Non-legend drugs are not provided except for the following: insulin and diabetic testing materials, antacid preparations, insulin syringes and needles, family planning drugs and devices, protein replacement supplements and other special items and pharmaceutical inhalation devices. The State does not cover, or grant prior authorization for, any drug that does not appear on the list of covered non-legend drugs.

In addition, coverage of the following non-legend drugs: analgesics/antipyretics, antihistamines, cough and cold preparations, decongestants, expectorants, iron supplements, laxatives and cathartics, topical and oral anti-inflammatory preparations, certain vitamins, and lice treatment products is limited to individuals under the age of twenty-one (21).

All initial prescriptions shall be limited to a 34-day supply and all refills are limited to a 34-day supply or 100 unit doses, whichever is greater, with not more than five refills in a six-month period.

Prior authorization is required for antiobesics or anorexics that may be used for the treatment of Attention Deficit Disorders (ADD), methadone for non-addiction use, protein nutrition supplements, and specialized infant formulas. Lipase inhibitors are subject to prior approval and shall be limited to certain obese individuals, based on Body Mass Index with or without certain co-morbidities.

Prior authorization is required through a phased-in medical exception process for prescribed drugs which exceed prospective drug utilization review (PDUR) standards recommended by the New Jersey Drug Utilization Review Board and approved by the Commissioner. Certain drugs subject to the medical exception process may require prior authorization prior to dispensing the initial supply. For other drugs subject to the medical exception process, an initial 30-day supply of medication can be issued by the pharmacy without prior authorization. During the 30-day period, the prescriber must provide written justification for continuing drug therapy beyond a drug utilization review standards. No payment will be made beyond the 30-day period without prior authorization. In emergencies, a 72-hour supply, or up to a six (6) day supply, may be dispensed before obtaining prior approval. The prior authorization process provides for a turn-around response by either telephone or other telecommunications device within twenty-four hours of receipt of a prior authorization request.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

LIMITATIONS ON AMOUNT, DURATION AND SCOPE OF SERVICES PROVIDED TO THE CATEGORICALLY NEEDY

Prior authorization is required when the number of prescriptions exceeds a State-specified amount in a calendar month. The State-specified amount of prescriptions does not include prescriptions for emergencies, in which case a 72-hour supply, or up to a six (6) day supply, may be dispensed before obtaining prior approval. The prior authorization process provides for a turn-around response by either telephone or other telecommunications device within twenty-four hours of receipt of a prior authorization request. Prior authorization is not required for pharmaceutical services to a resident in a nursing facility or in an assisted living residence, comprehensive personal care home or residential health care facility, or for prescriptions for clozapine, antihemophiliac drugs, immunosuppressants, and HIV/AIDS drugs (limited to protease inhibitors, antiretroviral drugs, nucleoside analogs and reverse transcriptase inhibitors). The least expensive, therapeutically effective protein nutritional supplements or specialized infant formulas shall be dispensed if the prescriber has not indicated "brand medically necessary" on the prescription.

Reimbursement is not available for unit-dose packaged drug products dispensed to residents in a boarding home, residential care setting, or other community-type setting. Other community-type settings shall not include certain assisted living settings, including assisted living residences (ALRs), comprehensive personal care homes (CPCHs), and alternative family care (AFC) homes licensed by the Department of Health and Senior Services. Drug products which are commercially available only as a unit-dose product are covered when not otherwise marketed as a chemically equivalent product.

Pharmacies providing unit-dose packaged drugs to NJFC/Medicaid beneficiaries residing in long term care and assisted living facilities are required to credit original payments to the State for individual doses of those drugs returned to the pharmacy for redispensing purposes.

Medical services, medical procedures or prescription drugs whose use is to promote or enhance fertility are not a covered service.

For claims with service dates on or after July 1, 1998, all impotency drugs shall be limited to male beneficiaries over age 18 and shall be limited to four (4) treatments per month.

For claims with services dates on or after July 1, 1998, prescribers must write "Diagnosis of Impotence" on the face of any prescription for impotency drugs. If that statement has not written by the prescriber on the face of the prescription, payment for the impotency drug shall be subject to recoupment by the State of New Jersey.

OFFICIAL

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
LIMITATIONS ON AMOUNT, DURATION AND SCOPE OF SERVICES
PROVIDED TO MEDICALLY NEEDY GROUPS
PREGNANT WOMEN, DEPENDENT CHILDREN, AND THE AGED, BLIND OR DISABLED

12(a) Pharmacy services

Coverage for drugs is available, limited to the following:

Multisource generic and single source brand name drugs shall be dispensed without prior authorization, but multisource brand name drugs shall not be dispensed without prior authorization by the State. However, a ten (10) day supply of the multisource brand name drug shall be dispensed pending receipt of prior authorization. Multisource brand name drugs with a narrow therapeutic index, certain other drugs recommended by the NJ Drug Utilization Review Board, or brand name drugs with a lower cost per unit than the generic drug may be excluded from prior authorization, as determined by the Commissioner. In emergency situations, providers may dispense at least a seventy-two hour supply of medication. The prior authorization process provides for a turn-around response by either telephone or other telecommunications device within twenty-four hours of receipt of a prior authorization request.

Covered outpatient drugs from any manufacturer that has entered into and complies with an agreement with the State on the same basis as provided under Section 1927(a) through (c) of the Act, which are prescribed for a medically accepted diagnostic indication (as provided by Section 1927(d) of the Act, certain outpatient drugs may be excluded from coverage).

Non-legend drugs are not provided except for the following: insulin and diabetic testing materials, antacid preparations, insulin syringes and needles, family planning drugs and devices, protein replacement supplements and other special items and pharmaceutical inhalation devices. The State does not cover, or grant prior authorization for, any drug that does not appear on the list of covered non-legend drugs.

In addition, coverage of the following non-legend drugs: analgesics/antipyretics, antihistamines, cough and cold preparations, decongestants, expectorants, iron supplements, laxatives and cathartics, topical and oral anti-inflammatory preparations, certain vitamins, and lice treatment products is limited to individuals under the age of twenty-one (21).

All initial prescriptions shall be limited to a 34-day supply and all refills are limited to a 34-day supply or 100 unit doses, whichever is greater, with not more than five refills in a six-month period.

Prior authorization is required for antiobesics or anorexics that may be used for the treatment of Attention Deficit Disorders (ADD), methadone for non-addiction use, protein nutrition supplements, and specialized infant formulas. Lipase inhibitors are subject to prior approval and shall be limited to certain obese individuals, based on Body Mass Index with or without certain co-morbidities.

Prior authorization is required through a phased-in medical exception process for prescribed drugs which exceed prospective drug utilization review (PDUR) standards recommended by the New Jersey Drug Utilization Review Board and approved by the Commissioner. Certain drugs subject to the medical exception process may require prior authorization prior to dispensing the initial supply. For other drugs subject to the medical exception process, an initial 30-day supply of medication can be issued by the pharmacy without prior authorization. During the 30-day period, the prescriber must provide written justification for continuing drug therapy beyond a drug utilization review standards. No payment will be made beyond the 30-day period without prior authorization. In emergency situations, providers may dispense at least a seventy-two hour supply of medication. The prior authorization process provides for a turn-around response by either telephone or other telecommunications device within twenty-four hours of receipt of a prior authorization request.

OFFICIAL

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
LIMITATIONS ON AMOUNT, DURATION AND SCOPE OF SERVICES
PROVIDED TO MEDICALLY NEEDY GROUPS
PREGNANT WOMEN, DEPENDENT CHILDREN, AND THE AGED, BLIND OR DISABLED

Prior authorization is required when the number of prescriptions exceeds a State-specified amount in a calendar month. The State-specified amount of prescriptions does not include prescriptions for emergencies, in which case a 72-hour supply, or up to a six (6) day supply, may be dispensed before obtaining prior approval. The prior authorization process provides for a turn-around response by either telephone or other telecommunications device within twenty-four hours of receipt of a prior authorization request. Prior authorization is not required for pharmaceutical services to a resident in a nursing facility or in an assisted living residence, comprehensive personal care home or residential health care facility, or for prescriptions for clozapine, antihemophiliac drugs, immunosuppressants, and HIV/AIDS drugs (limited to protease inhibitors, antiretroviral drugs, nucleoside analogs and reverse transcriptase inhibitors). The least expensive, therapeutically effective protein nutritional supplements or specialized infant formulas shall be dispensed if the prescriber has not indicated "brand medically necessary" on the prescription.

Reimbursement is not available for unit-dose packaged drug products dispensed to residents in a boarding home, residential care setting, or other community-type setting. Other community-type settings shall not include certain assisted living settings, including assisted living residences (ALRs), comprehensive personal care homes (CPCHs), and alternative family care (AFC) homes licensed by the Department of Health and Senior Services. Drug products which are commercially available only as a unit-dose product are covered when not otherwise marketed as a chemically equivalent product.

Pharmacies providing unit-dose packaged drugs to NJFC/Medicaid beneficiaries residing in long term care, assisted living facilities, comprehensive personal care homes (CPCHs), and alternative family care (AFC) homes licensed by the Department of Health and Senior Services are required to credit original payments to the State for individual doses of those drugs returned to the pharmacy for re-dispensing purposes.

Medical services, medical procedures or prescription drugs whose use is to promote or enhance fertility are not a covered service.

For claims with service dates on or after July 1, 1998, all impotency drugs shall be limited to male beneficiaries over age 18 and shall be limited to four (4) treatments per month.

For claims with services dates on or after July 1, 1998, prescribers must write "Diagnosis of Impotence" on the face of any prescription for impotency drugs. If that statement has not written by the prescriber on the face of the prescription, payment for the impotency drug shall be subject to recoupment by the State of New Jersey.

Prescribed drugs are available to pregnant women and dependent children. Non-dually-eligible beneficiaries enrolled in managed care who are aged, blind or disabled shall receive prescribed drugs on a fee-for-service basis.

TN 03-05-MA (NJ) Approval Date APR 16 2004
Supersedes TN 00-10 Effective Date JUL 01 [illegible]

PHARMACEUTICAL SERVICES

Payment for drugs shall be as follows:

1.16 Basis of payment

(a) Payment for legend drugs (those drugs whose labels include the legend "Caution: Federal Law Prohibits Dispensing Without a Prescription"), contraceptive diaphragms and reimbursable devices will be based upon the maximum allowable cost. This means the lower of the upper payment limit price list (MAC price) as published by the Federal government or the average wholesale price (AWP).

1. Maximum allowable cost is defined as:

   i. The MAC price for listed multi-source drugs published periodically by the Centers for Medicare & Medicaid Services (CMS) of the United States Department of Health and Human Services; or

   ii. For legend drugs not included in (a)1i above, the Estimated Acquisition Cost (EAC), which is defined as the average wholesale price (AWP) listed for the package size (billed to the New Jersey Medicaid program), in current national price compendia or other appropriate sources (such as the First Data Back (FDB) reference drug file contractor), and their supplements, minus a 12.5 percent volume discount.

2. If the published MAC price as defined in (a)1i above is higher than the maximum allowable cost which would be paid as defined in (a)1ii above, then (a)1ii above shall apply.

(b) The calculated discount shall be automatically deducted, regardless of prescription cost, by the fiscal agent, from the cost of each covered drug or device during claim processing by the New Jersey Medicaid Management Information System (NJMMIS).

TN 03-05-MA (NJ) Approval Date APR 16 2004
Supersedes TN 96-29 Effective Date JUL 01 2003

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1.17 Prescription dispensing fee

(a) The dispensing fee for legend drugs, dispensed by providers having retail permits, to beneficiaries other than those in nursing facilities, shall be established by State regulation. Additional dispensing fees (add-ons) per prescription shall be given to pharmacy providers who provide the following:

1. Twenty-Four Hour Emergency Service: The provider shall have a 24-hour per day, 365 days per year prescription service available and shall have provided Medicaid beneficiaries opportunities to utilize this service.

2. Patient Consultation: In addition to routinely monitoring beneficiary files for drug interactions, contraindications, allergies, etc., the provider shall, where appropriate, discuss the course of drug therapy with the beneficiary. This discussion must include emphasis on compliance with the prescriber's orders; proper drug utilization; cautions about possible side effects; foods to avoid; proper drug storage conditions; and any other information that will prove beneficial to the beneficiary while on drug therapy.

3. Impact Area Location: The provider shall have a combined Medicaid and PAAD prescription volume equal to or greater than 50 percent of the provider's total prescription volume.

i. The nursing facility prescription volume shall be included for the determination of total prescription volume in determining entitlement to the impact allowance.

(b) Price information is supplied from a reference drug file subcontracted for this purpose by the fiscal agent and accepted by the Division as the primary source of pricing information for the New Jersey Medicaid Management Information System (NJMMIS). The calculated price shall not exceed the lower of the average wholesale price (AWP) or the Federal Financial Participation Upper Limit (FFPUL) as supplied by the reference drug file contractor.

(c) In order to receive any or all of the above increments, the provider shall certify annually to the Division on Form FD-70, that the service(s) as defined in (a) above are being provided, and/or that the provider is entitled to the impact increment as defined in (a) above.

TN 03-05-MA (NJ) Approval Date APR 16 2004
Supersedes TN 96-29 Effective Date JUL 01 2003

1. Each claimed increment is subject to audit and retroactive recovery with appropriate penalties, if warranted, if the New Jersey Medicaid program determines that the provider was not entitled to reimbursement for them.

1.18 Capitation of dispensing fee for legend drugs to long-term care patients

(a) The New Jersey Medicaid program capitates the dispensing fee for legend drugs for patients in Medicaid approved long-term care facilities in accordance with the total number of Medicaid patient days in the facility(ies) serviced by the pharmacy. The capitation fee is established by regulation.

1. Pharmacies with retail permits dispensing medication in a dispensing system in which a 24-hour supply of unit dose oral medication, both solid (i.e. tablets, capsules) and liquid formulations, is delivered for each patient daily, will be reimbursed the cost of all reimbursable legend medication pus a fee per patient day.

i. Exception: Certain liquid medications that are supplied in concentrate form only and are administered by drop dosage cannot be supplied in a 24-hour dose.

2. Pharmacies with a retail permit dispensing medications in a dispensing system in which up to a one month supply or oral unit dose solid medication is delivered for each patient (i.e., unit dose solids modified unit dose system) will be reimbursed the cost of all reimbursable legend medication plus a fee per patient day.

3. Pharmacies with a retail permit dispensing medication in a dispensing system in which a maximum one month supply of medication is delivered for each patient will be reimbursed the cost of all reimbursable legend medication plus a fee per patient day.

4. Pharmacies which provide ancillary computerized services, such as, but not limited to, continuously updated patient profiles, clinical records (med sheets and physicians' orders on at least a monthly basis), etc., will receive an added increment per patient day.

5. Pharmacies with institutional permits will be reimbursed as above, except that the daily per patient capitation fee will be 75 percent of the fee for pharmacies with retail permits.

TN 03-05-MA (NJ) Approval Date APR 16 2004
Supersedes TN 96-29 Effective Date JUL 01 2003

OFFICIAL

1.19 Maximum charges - long-term care

(a) The maximum charge to the New Jersey Medicaid program for pharmaceutical services provided in a nursing facility, including the drug cost and related capitation fee, shall be equal to the lower of:

1. MAC/EAC plus capitation fee, as outlined above; or

2. A provider's usual and customary charge for long-term care pharmacy services, which is defined as the charge for legend drugs, including drug costs and related pharmaceutical services provided to non-Medicaid residents in the same facility, based on terms within the same contractual agreement with the facility.

(b) Providers of pharmaceutical services in nursing facilities are required, upon request by the Division of Medical Assistance and Health Services (DMAHS) or its authorized agent, to provide documentation supporting their usual and customary charges, including any relevant contracts and/or agreements related to similar services

(c) Pharmacies using more than one drug distribution system at a nursing facility will receive reimbursement for all legend drugs based on the lowest priced distribution system supplied to that nursing facility.

1.20 Legend drugs; total charge

(a) The maximum charge to the New Jersey Medicaid program for a legend drug, including the charge for the cost of medication and the dispensing fee, may not exceed the cost of the following:

1. MAC/EAC plus capitation fee, as outlined above; or

2. Usual and customary and/or posted or advertised charges; or

3. Other third-party prescription plan payments.

1.21 Compounded prescriptions

(a) Any prescriptions containing two or more ingredients in usually accepted therapeutic dosage and combined by a pharmacist at the time of dispensing is a compounded prescription and will be charged as follows:

TN 03-05-MA (NJ) Approval Date APR 16 2004
Supersedes TN 97-19 Effective Date JUL 01 2003

1. Total ingredient cost as defined in Section 1.16(a)1. The provider may charge up to $0.25 for any ingredient whose "cost" is less than $0.25; plus

2. The dispensing fee as allowed in Section 1.17.

3. The maximum charge for a compounded prescription will not exceed the limits set forth in Section 1.19.

(b) The maximum charge for a compounded prescription will not exceed the limits set forth in Section 1.19.

1.22 Non-legend drugs

(a) The only non-legend drug products that are eligible for reimbursement under the New Jersey Medicaid program are:

1. Insulin, diabetic testing materials, insulin syringes and needles;

2. Antacids;

3. Family planning materials and supplies;

4. Protein replacement supplements and other special items;

5. Pharmaceutical inhalation devices

(b) The maximum allowance for non-legend drug products under the New Jersey Medicaid program, is determined by the lower of:

1. The Estimated Acquisition Cost (EAC), which is defined as the average wholesale price (AWP) listed for the package size (billed to the New Jersey Medicaid program), in current national price compendia or other appropriate sources (such as the First Data Back (FDB) reference drug file contractor), and their supplements, minus a 12.5 percent volume discount; plus dispensing fee; or

2. The provider's usual and customary charge